

REMARKS

Favorable reconsideration of this application is respectfully requested in view of the claim amendments and following remarks. Claims 1 and 4-9 have been canceled without prejudice or disclaimer of the subject matter contained therein. Claims 10-15 have been added. Claims 2 and 3 have been amended. Currently, claims 2, 3, and 10-15 are pending in the present application of which claim 10 is independent. No new matter has been added.

In the specification, the title of the invention was objected to as being non-descriptive. The title has been amended in the current response. Claim 8 was objected to because of improper English. Claims 4-9 were objected to as being improper multiple dependent claims. The cancellation of Claims 4-9 renders these objections moot.

Claims 1-9 were rejected under 35 U.S.C. 101 as being improper process claims. Claims 1-6 and 8-9 were rejected under 35 U.S.C. 112, first paragraph, on the grounds that the specification provides insufficient enablement for all extracts from the Polypodium genus. Claims 1-9 were rejected under 35 U.S.C. 112, second paragraph, on the grounds that the claims fail to particularly point out and distinctly claim the invention. Claims 1-9 were rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 and 4-5 of U.S. Patent No. 5,601,829. Claims 1-5 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by McCan et al. (U.S. Patent Number 3,395,223). Claims 1-9 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Delgado de Chang (EP 0503208). Claims 1-9 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable

over Delgado de Chang (EP 0503208). The above objections and rejections are respectfully traversed for at least the reasons set forth below.

Claim Rejection Under 35 U.S.C. §101

Claims 1-9 were rejected under 35 U.S.C. 101 on the grounds that the claimed recitation of a use without setting forth any steps results in an improper process claim. Accordingly, Claim 1 has been cancelled, and replaced with newly presented claim 10. Claim 10 specifically recites a step of “administering to said subject an effective amount of an aqueous extract from Polypodium leucotomas, Phlebodium aureum, or Polypodium aureum.” Accordingly, Claim 10 specifically sets forth a step, and is therefore allowable under 35 U.S.C. 101. Claims 2, 3, and 11-15 depend from claim 10, and are therefore allowable under 35 U.S.C. 101 at least by virtue of their dependency.

Claim Rejection Under 35 U.S.C. §112

Claims 1-6 and 8-9 were rejected under 35 U.S.C. 112, first paragraph, on the grounds that the specification provides insufficient enablement for all extracts from the Polypodium genus. Accordingly, Claim 1 has been cancelled, and replaced with newly presented claim 10. Claim 10 is specifically limited to “an aqueous extract from Polypodium leucotomas, Phlebodium aureum, or Polypodium aureum.” The Examiner admits that support for Polypodium leucotomas is presented in the specification (Page 3 of the office action).

Additionally, support for *Phlebodium aureum* is provided in Paragraph [0031], and support for *Polypodium aureum* is provided in Paragraph [0032].

Claims 1-9 were rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner asserted that there was insufficient antecedent basis for the limitation “the polypodium extracts” in claim 1. The cancellation of claim 1 renders this rejection moot.

Claims 1-9 were rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for reciting a use without any active positive steps. Accordingly, Claim 1 has been cancelled, and replaced with newly presented claim 10. Claim 10 specifically recites a step of “administering to said subject an effective amount of an aqueous extract from *Polypodium leucotomas*, *Phlebodium aureum*, or *Polypodium aureum*.” Accordingly, Claim 10 specifically sets forth a step.

Double Patenting

Claims 1-9 were rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 and 4-5 of U.S. Patent No. 5,601,829. Withdrawal of this rejection is respectfully requested for at least the reasons set forth below. Claims 1, 4, and 5 of the ‘829 patent are drawn to a method of “producing a neuroprotective effect in a patient.”

Independent Claim 10 and the claims depending therefrom in the current application are drawn specifically to “treating a subject suffering from Peyronie’s disease.” Peyronie’s disease is not a neurodegenerative or neuroimmune disease as required by the ‘829 patent; rather, it is characterized by formation of dense, fibrous scar tissue (plaque) in the tunica albuginea of the penis. Accordingly, Claim 10 and all claims depending therefrom define a new use for Polypodium extracts which is significantly different from that described in the ‘829 patent. As stated in 35 U.S.C. 100(b), “The term ‘process’ means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”

Claim Rejection Under 35 U.S.C. §102

The test for determining if a reference anticipates a claim, for purposes of a rejection under 35 U.S.C. § 102, is whether the reference discloses all the elements of the claimed combination, or the mechanical equivalents thereof functioning in substantially the same way to produce substantially the same results. As noted by the Court of Appeals for the Federal Circuit in *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984), in evaluating the sufficiency of an anticipation rejection under 35 U.S.C. § 102, the Court stated:

Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.

Therefore, if the cited reference does not disclose each and every element of the claimed invention, then the cited reference fails to anticipate the claimed invention and, thus, the claimed invention is distinguishable over the cited reference.

Claims 1-5 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the disclosure contained in McCan (U.S. Patent Number 3,395,223). This rejection, which will be treated herein as if it had been applied to Claim 10, is respectfully traversed because the claimed invention as set forth in newly presented claim 10 and the claims that depend therefrom is patentably distinguishable over McCan. McCan teaches a method of obtaining a Polypodium extract using a polar solvent such as methanol or water. McCan further teaches that the extract is useful for treating gastrointestinal ulcerations.

Claim 10 recites that a subject suffering from Peyronie's disease may be treated by "administering an effective amount of an aqueous extract from Polypodium leucotomas, Phlebodium aureum, or Polypodium aureum." McCan fails to teach the treatment of Peyronie's disease recited in claim 10. Peyronie's disease is not a gastrointestinal disease as described by McCan; rather, it is characterized by formation of dense, fibrous scar tissue. Accordingly, Claim 10 and all claims depending therefrom define a new use for Polypodium extracts which is significantly different from that described by McCan.

Accordingly, McCan fails to teach all of the features contained in claim 10, and thus, this claims is believed to be allowable over McCan. Claims 2, 3, and 11-15 depend upon allowable claim 10 and are also allowable over McCan at least by virtue of their dependencies.

Claims 1-9 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the disclosure contained in Delgado de Chang (EP 0503208). This rejection, which will be treated herein as if it had been applied to Claim 10, is respectfully traversed because the claimed invention as set forth in newly presented claim 10 and the claims that depend therefrom is patentably distinguishable over Delgado de Chang. Delgado de Chang teaches a water soluble extract from the rhizomes of Polypodium which may be orally administered.

Claim 10 recites that a subject suffering from Peyronie's disease may be treated by "administering an effective amount of an aqueous extract from Polypodium leucotomas, Phlebodium aureum, or Polypodium aureum." Delgado de Chang fails to teach the treatment of Peyronie's disease, as recited in claim 10. Accordingly, Claim 10 and all claims depending therefrom define a new use for Polypodium extracts which is not anticipated by Delgado de Chang.

Accordingly, Delgado de Chang fails to teach all of the features contained in claim 10, and thus, this claims is believed to be allowable over Delgado de Chang. Claims 2, 3, and 11-15 depend upon allowable claim 10 and are also allowable over Delgado de Chang at least by virtue of their dependencies.

Claim Rejection Under 35 U.S.C. §103

The test for determining if a claim is rendered obvious by one or more references for purposes of a rejection under 35 U.S.C. § 103 is set forth in MPEP § 706.02(j):

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation,

either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Therefore, if the above-identified criteria are not met, then the cited reference(s) fails to render obvious the claimed invention and, thus, the claimed invention is distinguishable over the cited reference(s).

Claims 1-9 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Delgado de Chang; this rejection will be treated herein as if it additionally applied to Claim 10. This rejection is respectfully traversed because Delgado de Chang fails to teach or suggest the claimed invention as set forth in claim 10 and its dependents.

Delgado de Chang discloses a water soluble extract from the rhizomes of Polypodium which may be orally administered. Delgado De Chang further discloses that such extracts are effective against herpes zoster, multiple sclerosis, atopic dermatitis, ophthalmologic conditions, and viral ketoses (Page 2, line 51-Page 3, line 18).

Claim 10 recites a method for treating a subject suffering from Peyronie's disease with an aqueous extract of *Polypodium leucotomas*, *Phlebodium aureum*, or *Polypodium aureum*. The Official Action asserts that it would have been obvious to one of ordinary skill in the art to prepare a therapeutic water soluble extract from the rhizomes of *Polypodium*, based on the teachings of Delgado de Chang. However, the Applicants submit that Delgado de Chang fails to

teach or suggest treatment of Peyronie's disease, as recited in claim 10. No specific treatment of Peyronie's disease is described by Delgado de Chang, nor is Peyronie's disease even addressed as a condition that might be addressed by the Polypodium extract.

At least by virtue of Delgado de Chang's failure to teach or suggest the above identified element of claim 10, a *prima facie* case of obviousness has not been established under 35 U.S.C. § 103. Accordingly, the Examiner is respectfully requested to allow Claim 10 over Delgado de Chang. Claims 2, 3, and 11-15 depend from allowable claim 10 and are also allowable over Delgado de Chang at least by virtue of their dependencies.

Conclusion

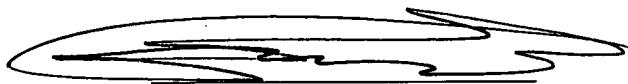
In light of the foregoing, withdrawal of the rejections of record and allowance of this application are earnestly solicited.

While we believe that the instant amendment places the application in condition for allowance, should the Examiner have any further comments or suggestions, it is respectfully requested that the Examiner telephone the undersigned attorney in order to expeditiously resolve any outstanding issues.

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Respectfully submitted,
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